K123144

JUN 18 2013

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	June 17, 2013
Establishment Number	9617566
Submitter:	GE Healthcare, BREAS MEDICAL AB Företagsvagen 1 Mölnlycke, SWEDEN 435 33
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US Agent:	Pam Schaub GE Healthcare 9900 w. innovation drrp2138 Wauwatosa, WI 53226 Phone: 414 7212584 ext Fax: 262 9971160 Email: pam.schaub@ge.com

Device Trade Name:	Vivo 50
Common/Usual Name:	Portable Ventilator
Classification Names and Product Code[s]:	CBK 21 CFR 868.5895, Continuous Ventilator NOU 21 CFR 868.5895, Continuous Ventilator, Home Use DQA 21 CFR 870.2700, Oximeter CCK 21 CFR 868.1400, Analyzer, gas, carbon-dioxide, gaseous-phase
Predicate Device(s):	iVent101 [cleared under K112754] Trilogy100 [cleared under K111610] VEO Multigas Monitor [cleared under K081601 & K123043]

Device Description:

The Vivo 50 Ventilator is a portable, microprocessor controlled turbine based pressure support, pressure control or volume controlled ventilator intended for the care of individuals who require mechanical ventilation.

Internal flow and pressure are read through flow/ pressure sensors. Essential parameters such as pressure, flow and volume are presented on the ventilator screen, both as graphs and numbers.

All the operator actions are performed via the front panel where clear buttons and screen are located. There are dedicated LEDs and buttons for managing alarm conditions and an Information button which provides integrated user support.

The Vivo 50 can be operated by external AC or DC power supply and contains an integrated battery as well as an additional click on battery.

The Vivo 50 can be used with both single limb patient circuits including an active exhalation valve and single limb patient circuits including a leakage port.

The Vivo 50 can be operated in 9 different ventilation modes:

- PSV – Pressure Support Ventilation
- PSV(TgV) – Pressure Support Ventilation with Target Volume

- PCV – Pressure Controlled Ventilation
- PCV(TgV) – Pressure Controlled Ventilation with Target Volume
- PCV(A) – Assisted Pressure Controlled Ventilation
- PCV(A+TgV) – Assisted Pressure Controlled Ventilation with Target Volume
- VCV – Volume Controlled Ventilation
- VCV(A) – Assisted Volume Controlled Ventilation
- CPAP – Continuous Positive Airway Pressure

The internal memory data of the Vivo 50 can be downloaded to a PC, printed out, and analysed via the Vivo 50 PC Software. The Vivo 50 PC Software is the support software for follow-up on patient treatment. The PC Software can communicate with the ventilator in two ways, either using an USB cable or a Compact Flash memory card.

The Vivo 50 PC Software provides presentation features of logged data by 24 hours, 30 days and 365 days resolution. The Vivo 50 PC Software presents treatment parameters such as pressure, volume, flow, leakage but also events such as alarms and change of settings. Further, the hours of usage is presented.

The Vivo 50 with the iOxy kit , consisting of an SpO2 (blood oxygen saturation) Nonin sensor, an electronic unit and cable, is intended to be connected to ventilator for logging SpO2 and pulse rate data and, when applicable, for real time monitoring. The SpO2 and pulse rate measurements are stored in the Vivo 50 internal memory log which can be downloaded to a PC and viewed in the Vivo 50 PC software. The SpO2 sensors are manufactured by Nonin Medical Inc.

The Vivo 50 with the CO2 sensor can be connected with the purpose to measure and display End Tidal CO2 (EtCO2) as well as Inspired CO2 (InspCO2). The EtCO2 displays the end-tidal carbon dioxide, measured on the last portion of the exhaled volume. The InspCO2 displays the inspired carbon dioxide.

The CO2 sensor can be connected to the patient breathing circuit and to the Vivo 50 in order to monitor and store CO2 measurements. The CO2 measurements will be stored in the Vivo 50 data memory which can be downloaded to a PC and viewed in the Vivo 50 PC software.
The CO2 sensor used with the Vivo 50 is manufactured by PHASEIN AB and is in used with PHASIEN AB carbon dioxide gas analyser cleared device under K081601 & K123043.

The Vivo 50 Remote Alarm Unit enables care providers and clinical personnel to monitor the Vivo 50 alarms remotely. The Remote Alarm unit is connected to the ventilator via a 10, 25 or 50 meter cable and powered by the ventilator. The Remote Alarm repeats alarms from the Vivo 50. The alarm signal sound level may be adjusted by the user. The actions or adjustments on the Remote Alarm unit do not, in any way, affect the alarm indications, alarm sound level, or audio pause on the Vivo 50.

Indications for use :

The Vivo 50 ventilator (with or without the iOxy and CO_2 sensor) is intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. Specifically, the ventilator is applicable for pediatric through adult patients weighing at least 10 kg (22 lbs.).

The Vivo 50 with the iOxy is intended to measure functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate.
The Vivo 50 with the CO_2 sensor is intended to measure CO_2 in the inspiratory and expiratory gas.

The device is intended to be used in home, institution, hospitals and portable applications such as wheelchairs and gurneys. It may be used for both invasive and non-invasive ventilation. The Vivo 50 is not intended to be used as a transport and critical care ventilator.

Technological Characteristics:

The Vivo 50 employs the same fundamental scientific technology as the following predicate devices, including equivalent turbine ventilator technology and equivalent software algorithms to control ventilation modes and monitoring functionality:

- iVent101 [cleared under K112754]
- Trilogy100 [cleared under K111610]
- VEO Multigas Monitor [cleared under K081601& K123043]

The Vivo 50 shares the same intended use, use environment and target patient population as its predicate devices.

Summary of Non-Clinical Tests:

The Vivo 50 ventilator has been thoroughly tested through verification of specifications and validation, including software validation. Verification of compliance with applicable standards has also been completed to ensure safe use of the device in its intended use environment, including electrical safety and electromagnetic compatibility testing. The following quality assurance measures were applied during the development of the Vivo 50 ventilator system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Integration testing
- Performance testing
- Safety testing / including Standards compliance testing
- Simulated use testing

Summary of Clinical Tests:

The subject of this premarket submission, Vivo 50 did not require clinical studies to support substantial equivalence.

No performance standards have been established for such devices under Sections 514 of the Federal Food, Drug, and Cosmetic Act. However, the Vivo 50 complies with the following voluntary standards and guidance documents:

- Draft Reviewer guidance for ventilators
- Draft Guidance for industry and FDA staff – Pulse Oximeters- Premarket notification submissions
- Draft Guidance for Industry and FDA Staff - Pulse Oximeters
- FDA Guidance for the content of Premarket submissions for software contained in Medical Devices
- ASTM F1246-91, Electrically Powered Home Care ventilators, Part 1: Positive-Pressure Ventilators and Ventilator Circuits
- ASTM F1100, Standard specification for ventilators intended for Use in Critical Care [for waveform standard analysis between the Vivo 50 and the predicate devices]

- IEC 60601-1, Medical Electrical Equipment – General requirements for safety

- IEC 60601-1-2, Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests

- IEC 60601-1-8, General requirements for safety – collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

- IEC 62304, Medical device software -- Software life cycle processes

- IEC 60601-1-6, Medical Electrical Equipment – Part 1-6: General requirements for safety – collateral standard: Usability

- IEC 62366, Medical devices - Application of usability engineering to medical devices

- IEC 60601-1-4, Medical electrical equipment: part 1-4: general requirements for collateral standard: programmable electrical medical systems

- ISO 9919, Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use

- ISO 21647, Medical electrical equipment - Particular requirements for the basic safety and essential performance of respiratory gas monitors

- EN ISO 10651-2, Lung Ventilators for medical use – Particular requirements for basic safety and essential performance – Part 2: Home Care Ventilators for ventilator dependent patients

- EN ISO 10651-6, Lung Ventilators for medical use – Particular requirements for basic safety and essential performance – Part 6: Home care ventilator support devices

Substantial Equivalence Conclusion:

Based on the performance testing, GE Healthcare considers the Vivo 50 to perform in a substantially equivalent manner, as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 18, 2013

Mr. Shlomi Deler
Regulatory Affairs Manager
GE Healthcare, BREAS MEDICAL AB
Foretagsvagen 1
Molnlycke, Sweden 43533

Re: K123144
Trade/Device Name: Vivo 50
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK, NOU, DQA, CCK
Dated: May 16, 2013
Received: May 21, 2013

Dear Mr. Deler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

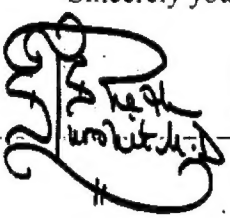
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



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Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Vivo 50

Indications for Use:

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Prescription Use_XXX_ AND/OR Over-The-Counter Use_
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

James J. Lee

Digitally signed by James J. Lee
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=James J. Lee, 0.9.2342.19200300.100.1.1=2000954859
Date: 2013.06.17 12:42:51 -04'00'

Acting BC
for
Dr. Anya Harry

Page _1_ of _1_

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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